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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,107	12/29/2003	Hanson S. Gifford III	001-004-C1	3157
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HOEKENDIJK & LYNCH, LLP P.O. BOX 4787 BURLINGAME, CA 94011-4787			EXAMINER BAXTER, JESSICA R	
			ART UNIT 3733	PAPER NUMBER
DATE MAILED: 12/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/749,107

Applicant(s)

GIFFORD ET AL.

Examiner

Jessica R. Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION*****Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer.

A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-88 of U.S. Patent No. 6,712,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a device for lining a vessel comprising an expandable anchor, a liner an inner layer and an outer layer and a method for it's use.

3. Claim 38 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14, 16, 17 and 33 of U.S. Patent No. 6,383,171. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a method of opening a narrowed region in a blood vessel comprising the steps of providing a liner, advancing the liner, passing a portion of the liner through the narrowed region, positioning and expanding a stent in the liner.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,2,5,9,10,16,19,20 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,123,723 to Konya et al.

Konya discloses a device for lining a vessel comprising an expandable anchor (1), a liner (FIG. 15 graft), an inner layer (20) attached to an inner element (35), an outer layer (24) attached to an outer element (FIG. 20 catheter 26), lying directly over the anchor, the outer layer holding the anchor and liner in the collapsed position (FIG. 15).

Konya discloses a method of lining a vessel, comprising the steps of: providing an expandable anchor (200), a liner (204), an inner layer (218), and an outer layer (226), the anchor and liner being movable from a collapsed shape to an expanded shape, the liner being attached to the anchor and extending from an end of the anchor, the outer layer being slidable relative to the inner layer, the outer layer extending over the liner and the anchor extending over the liner and anchor in the collapsed position; advancing the device to a treatment site; and retracting the outer layer to expose the liner and the anchor to permit the anchor to expand (Column 29 line 40-Column 30 line 21).

Konya discloses a method of opening a narrowed region in a blood vessel, comprising the steps of: providing a liner movable from a collapsed condition to an expanded condition; advancing the liner to a narrowed region of a blood vessel with the liner in the collapsed position (FIG. 20); passing at least a portion of the liner through the narrowed region of the blood vessel in the collapsed position; positioning a stent in the liner so that the stent is also positioned in the narrowed region of the blood vessel, the liner preventing the stent from contacting the narrowed region of the blood vessel; and expanding the stent to open the narrowed region of the vessel (Column 29 line 40-Column 30 line 21).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 6, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konya et al. '723.

Konya discloses the claimed invention except for the claimed sizes of the outer layer thickness, the inner layer thickness, the outer layer diameter, and the collapsed anchor length. Konya discloses that different sizes of devices may be used (Column 29 lines 8-25) It would have been an obvious matter of design choice to change the size of the outer layer thickness, inner layer thickness, outer layer diameter, and collapsed anchor length since such

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a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

8. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konya et al. '723 in view of U.S. Patent No. 4,732,152 to Wallsten et al.

Konya discloses the claimed device except for the outer layer comprising a tapered portion that is stretched over as it is retracted. Wallsten discloses an alternative delivery catheter that has a stretchable outer layer that stretches over a tapered portion (FIG. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter of Konya with the outer layer of Wallsten since both will prevent the anchor and liner assembly from expanding until the outer layer is withdrawn.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Konya '723 in view of U.S. Patent No. 5,366,473 to Winston et al.

Konya discloses the claimed invention except for the folds in the graft. Winston discloses that folds in the graft allow the graft to be delivered at a smaller diameter before expansion (Column 3 lines 43-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the graft of Konya with the folds, as taught by Winston, in order to deliver the graft at a smaller diameter than without the folds.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Konya et al. '723 in view of U.S. Patent no. 5,843,166 to Lentz et al.

Konya discloses the claimed invention except for the liner being made of expanded PTFE. Lentz teaches that expanded PTFE is used to make liners since it has superior biocompatibility and exhibits low thrombogenicity and allows natural tissue ingrowth and thus contributes to long term healing and patency (Column 1 lines 41-51). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Konya with the material ePTFE since it is a material with superior biocompatibility that leads to long term healing and patency.

11. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konya et al. '723 in view of U.S. Patent No. 5,395,332 to Ressemann et al.

Konya discloses the claimed invention except for the radiopaque coil positioned at least partially between the inner and outer layers and beyond the distal end of the liner.

Ressemann teaches that a radiopaque coil is provided in between two layers at a distal end of an instrument in order to give the tip an intermediate stiffness and prevent kinking as the catheter travels through vessels. The radiopacity is provided so that the surgeon can locate the distal tip of the catheter (Column 14 lines 20-57). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Konya with the radiopaque coil of Ressemann in order to provide a means of locating the tip of the catheter and to prevent kinking as the catheter travels through the vessels.

#### ***Allowable Subject Matter***

12. Claims 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R. Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
jrb

Jessica R Baxter  
Examiner  
Art Unit 3733

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER